5. 510(K) SUMMARY

K070651

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: March 7, 2007

510(k) number: _____

MAY 30 2007

Applicant Information:

Aragon Surgical, Inc.
1810 Embarcadero Road, Suite B
Palo Alto, CA 94304

Device Information:

Trade Name:	Aragon Surgical LapCap
Classification:	Class II 21CFR 884.1730
Product Code:	HIF
Classification Name:	Laparoscopic Insufflator and Accessories

Physical Description:

The Aragon Surgical LapCap is a single-use device used during laparoscopic surgical procedures. The device consists of a bell-shaped polycarbonate dome housing containing a pass-through port for introduction of a standard Veress needle and a vacuum port for attachment to a standard hospital vacuum line.

Intended Use:

The Aragon Surgical LapCap is intended for use in the peri-umbilical region of the abdominal wall with a Veress needle for the establishment of a pneumoperitoneum during gynecologic (pelvic) and general surgical (intraabdominal) laparoscopic procedures.

Equivalent Device:

The subject device is substantially equivalent in intended use/technological characteristics and/or method of operation to the Veresure Bell (K061387) and the Taut – Insufflation Needle (K003703).

Summary:

Based on the intended use and technological characteristics information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 3 0 2007

Mr. Alan Curtis
Vice President Regulatory/Quality/Clinical Affairs
Aragon Surgical, Inc.
1810 Embarcadero Road Suite B
PALO ALTO CA 94303

Re: K070651
Trade/Device Name: Aragon Surgical LapCap
Regulation Number: 21 CFR 884.1730
Regulation Name: Laparoscopic insufflator
Regulatory Class: II
Product Code: HIF
Dated: April 19, 2007
Received: April 24, 2007

Dear Mr. Curtis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070651

Device Name: Aragon Surgical LapCap

Indications For Use:

The Aragon Surgical LapCap is intended for use in the peri-umbilical region of the abdominal wall with a Veress needle for the establishment of a pneumoperitoneum during gynecologic (pelvic) and general surgical (intraabdominal) laparoscopic procedures.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K070651